The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 53

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HIROKUMI TERASAWA, AKIO EJIMA,
SATORU OHSUKI, and KOUICHI UOTO

Appeal No. 1998-2587
Application No. 08/451,993

HEARD: April 3, 2001

Before WINTERS, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 14-25, 28, 37, and 38, all of the claims remaining in the application. Claim 1 is directed to a genus of hexacyclic compounds related to camptothecin; the structure of the claimed genus is shown on page 2 of the specification. Claims 14-23, 37, and 38 are directed to various subgenera of the genus of claim 1, claims 24 and 25 are directed to specific compounds within the genus of claim 1, and claim 28 is directed to a pharmaceutical composition

comprising a compound within the genus of claim 1. The claims are reproduced in Appendix I attached to the Appeal Brief.

The examiner relies on the following references:

European Patent Appliation
Terasawa et al. (Terasawa EP) 0 495 432 Jul. 22, 1992

Burger, Medicinal Chemistry, 2d Ed., Interscience, New York, p. 42 (1960)

Mitsui et al. (Mitsui), "Antitumor activity of DX-8951, a new camptothecin derivative, " Proceedings 84th Annual Meeting of the American Association for Cancer Research, Vol. 34, p. 421, (abstract 2510) (1993)

All of the claims stand rejected under 35 U.S.C. § 112, first paragraph, as non-enabled by the specification.

All of the claims stand rejected under 35 U.S.C. § 102(b) over Terasawa EP.

Claims 1, 14-20, 25, 28, 37, and 38 stand rejected 35 U.S.C. § 102(b) over Mitsui.

Claim 25 stands provisionally rejected for obviousness-type double patenting over claim 1 of copending application 08/501,933.

We reverse all of the rejections.

Background

Appellants' specification discloses that camptothecin is a pentacyclic alkaloid compound which is known to have antitumor activity. Page 1. Camptothecin, however, is too toxic and too water-insoluble to be used therapeutically. Id. The specification discloses a genus of camptothecin-derived

hexacyclic compounds which "have an excellent antitumor activity and a high degree of safety, and are water-soluble." Id., page 12.

Discussion

1. The non-enablement rejection.

The examiner rejected the all of the claims because, in his view, undue experimentation would be required to practice the full scope of the claims. The examiner argues, for example, that not all combinations of the R_1, R_2, and R_4 groups encompassed by claim 1's generic formula will have the appropriate water solubility and lipophilicity to be pharmaceutically useful, and that the specification does not enable those skilled in the art to use them in other ways, e.g., as prodrugs. Examiner's Answer, pages 7-10, 12, 13-15. The examiner also argues that starting materials are not available to make some of the compounds that are encompassed by the generic formula (Answer, pages 10, 11-12, 13), and that claims 24 and 25 are not limited to "physiologically acceptable" salts and therefore encompass toxic or insoluble salts of the recited compounds, which the specification does not teach how to use (Answer, pages 10-11).

Appellants dispute the potential problems pointed to by the examiner. However, even assuming arguendo that all of the examiner's critiques have merit, we conclude that the examiner has not made out a prima facie case of non-enablement.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The examiner has pointed to several problems that might be encountered by a skilled artisan who tried to make and use certain compounds encompassed by the claims. The gist of the examiner's reasoning is that the claims encompass inoperative embodiments and therefore a skilled artisan could not make and use each and every compound encompassed by the claims without undue experimentation.

The enablement standard imposed by the examiner is more stringent than is supported by the case law. "The fact that some experimentation is necessary does not preclude enablement. . . . 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.'" PPG Indus. Inc. v. Guardian Indus. Corp, 75 F.3d 1558, 1564, 37

USPQ2d 1618, 1623 (Fed. Cir. 1996) (quoting Ex parte Jackson, 217 USPQ 804, 807 (Bd. App. 1982)). See also In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) ("That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" (emphasis in original); In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976) ("The key word is 'undue,' not 'experimentation.'").

The fact that a claim encompasses inoperative embodiments does not necessarily make the claim non-enabled. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984). Of course, "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be [non-enabled]." Id. The potential difficulties pointed out by the examiner are not sufficient to show that the number, if any, of inoperative embodiments encompassed by the claims is so large that undue experimentation would be required practice the claimed invention.

The examiner also seems not to have fully considered all of the Wands factors, including the state of the art, the level of skill in the art, and the guidance provided by the specification. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Organic chemistry is a well-established field and practiced by researchers with a high degree of skill. Surely those skilled in the art would be aware that certain salts would be likely to be toxic or water-

insoluble, and therefore unsuitable for use in a pharmaceutical composition. Likewise, those skilled in the art would certainly be aware that t-butyl groups are bulky substituents and therefore likely to present steric hindrance problems if situated on adjacent carbon atoms. Finally, we note that the specification provides fifty working examples of various camptothecin derivatives. In this case all these factors weigh in favor of enablement. The examiner does not address these factors, focusing only on the unpredictability and potential inoperability of certain embodiments encompassed by the claims.

Having considered the record as a whole, we conclude that the examiner's position is not supported by a preponderance of the evidence. We therefore reverse the rejection for non-enablement.

2. The rejections for anticipation.

The examiner rejected all of the claims as anticipated by Terasawa EP and rejected claims 1, 14-20, 25, 28, 37, and 38 as anticipated by Mitsui. Appellants do not dispute that both Terasawa EP and Mitsui identically disclose the compounds of the instant claims, but argue that neither reference is prior art. According to Appellants, the instant application is a continuation of application 08/112,230, filed August 27, 1993, which was a continuation of 07/820,232, filed January 14, 1992.

The examiner argues that Appellants are not entitled to claim an earlier filing date under 35 U.S.C. § 120 because the earlier-filed applications did not enable the instant claims, for the same reasons the instant application does not

enable them. The examiner therefore argues that both Terasawa EP and Mitsui are available as prior art.

We agree with the examiner that a claim must be enabled by a priority document in order to gain the benefit of an earlier effective filing date under 35 U.S.C. § 120. See In re Hogan, 559 F.2d 595, 604, 194 USPQ 527, 536 (CCPA 1977) ("[S]ymmetry in the law, and evenness of its application, require that § 120 be held applicable to all bases for rejection, that its words 'same effect' be given their full meaning and intent.") Accord, Transco Prods. Inc. v. Performance Contracting Inc., 38 F.3d 551, 557, 32 USPQ2d 1077, 1082 (Fed. Cir. 1994) (§ 120 requires compliance with all the requirements of the first paragraph of § 112). Therefore, we reject Appellants' argument that they "are entitled to the filing date of January 14, 1992 pursuant to 35 U.S.C. § 120, regardless of the sufficiency of disclosure." Appeal Brief, page 5 (emphasis in original).

However, we have already concluded that the instant claims are enabled by the instant specification. See pages 3 to 6, supra. The examiner has not suggested that the degree of enablement provided by the parent applications differs from that of the instant application; the disclosures are apparently identical. Therefore, the claims were apparently enabled by the parent specifications and are therefore entitled to the benefit of priority under § 120. The effective filing date of the instant claims is January 14, 1992. Neither Terasawa EP nor Mitsui are prior art, so neither can form the basis of a rejection under 35 U.S.C. § 102.

3. The rejection for obviousness-type double patenting.

The examiner provisionally rejected instant claim 25 on the basis that it is not patentably distinct from claim 1 of co-pending application 08/501,933. Instant claim 25 is directed to a specific hexacyclic compound "or a salt thereof." Claim 25 does not specify the stereochemistry of the claimed compound at the 1 carbon.

Claim 1 of the '933 application is directed to the methanesulfonate salt of the (1S) stereoisomer of the same compound. The examiner reasoned that the methanesulfonate salt is an obvious species because it is mentioned in the instant specification as a potentially useful salt, and that isolating the (1S) stereoisomer would have been obvious because "the U.S. F.D.A. has been encouraging the clearance of specific isomer, [so] resolving and choosing the more active isomer would be obvious." Examiner's Answer, page 16.

"Obviousness-type double patenting . . . requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later." In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).

The examiner has not established that claim 1 of the '993 application and instant claim 25 are not patentably distinct. The examiner has pointed to nothing

in the record that would have motivated those skilled in the art to resolve the racemic mixture of instant claim 25 and isolate the (1S) stereoisomer. Even when obviousness is based on a single reference, that reference must contain some suggestion or motivation to modify its teachings in order to produce the claimed compound. See In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000); In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984). The examiner's unsupported reference to the practices of the Food and Drug Administration cannot be relied on to provide the required motivation. The provisional rejection is reversed.

Other Issues

Appellants' U.S. Patent 5,658,920, issued Aug. 19, 1997, claims the hydrochloride and methanesulfonate salts of the compound of instant claim 25. Neither instant claim 25 nor the claims of the '920 patent specify a particular position 1 stereoisomer. The examiner should consider whether the specific salts claimed in the '920 patent are patentably distinct from the generic salt recited in instant claim 25. If they are not patentably distinct, a rejection of instant claim 25 for obviousness-type double patenting would be appropriate.

Summary

The examiner has not shown, by a preponderance of the evidence, that undue experimentation would have been required to practice the full scope of the claimed invention. We therefore reverse the rejection for non-enablement and, consequently, the rejections for anticipation. We also reverse the provisional

rejection for obviousness-double patenting because the examiner has not shown that the conflicting claims are not patentably distinct.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	))))) BOARD OF PATENT
TONI R. SCHEINER Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
ERIC GRIMES Administrative Patent Judge	))

OBLON SPIVAK McCLELLAND
MAIER & NEUSTADT
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EG/jlb